

2123/JFW



ATTORNEY DOCKET NO. 14014.0410U1
SERIAL NO. 10/517,898

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of)	
)	
Strober, et al.)	Art Unit: 2123
)	
Application No. 10/517,898)	Examiner: Unassigned
)	
Int'l. Filing Date: June 14, 2002)	Confirmation No. 5707
)	
For: "METHODS OF TREATING AND)	
PREVENTING COLITIS INVOLVING,)	
IL-13 AND NK-T CELLS")	

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

NEEDLE & ROSENBERG, P.C.
Customer Number 36339

Sir:

Pursuant to the requirements of 37 C.F.R. § 1.56, submitted herewith on the accompanying Information Disclosure Statement List is a listing of documents known to Applicants and/or their attorneys. In accordance with 37 C.F.R. §1.98(a)(2), copies of any cited U.S. patent or U.S. patent application publication documents are not enclosed. Copies of any cited foreign patent document and/or any non-patent publication are enclosed.

This Information Disclosure Statement is believed to be filed in a timely manner pursuant to 37 C.F.R. § 1.97(b)(3), in that a first Office Action on the merits of the present patent application has not yet been mailed to Applicants.



ATTORNEY DOCKET NO. 14014.0410U1
SERIAL NO. 10/517,898

Consideration of the cited documents and making the same of record in the prosecution of the above-referenced application are respectfully requested.

No fee is believed due; however, the Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

NEEDLE & ROSENBERG, P.C.

Lizette M. Fernandez, Ph.D.
Registration No. 46,694

NEEDLE & ROSENBERG, P.C.
Customer Number 36339
(678) 420-9300
(678) 420-9301 (fax)

CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence, including any items indicated as attached or included, is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendments, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date indicated below.

Lizette M. Fernandez, Ph.D.

Date

10/14/05



INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)		Complete if Known					
		Application Number		10/517,898			
		Filing Date		14 June 2002			
		First Named Inventor		Warren Strober			
		Group Art Unit		2123			
		Examiner Name		Unassigned			
U.S. PATENT DOCUMENTS							
Examiner's Initials	Cite No.	Document No.	Date	Name	Class	Subclass	Filing Date (if appropriate)
	B1	2002/0042387	04/11/02	Eyal et al.			
	B2	6,143,871	11/07/00	Bonnefoy et al.			
	B3	5,614,191	03/25/97	Puri et al.			
	B4	6,518,061	02/11/03	Puri et al.			
	B5	2004/0043921	03/04/04	Bonnefoy et al.			
FOREIGN PATENT DOCUMENTS							
Examiner's Initials	Cite No.	Foreign Patent Document Country Code-Number- Kind Code	Date	Name	Translation Yes/No		
	B6	WO 00/02923	01/20/00	Nickoloff			
	B7	WO 00/02583	01/20/00	Nickoloff			
NON-PATENT DOCUMENTS							
Examiner's Initials	Cite No.	Non-Patent Citations (include Author, Title, Publisher, Relevant Pages, Date and Place of Publication)					
	B8	Balk, S. P., Bleicher, P. A., and Terhorst, C. (1989). Isolation and characterization of a cDNA and gene coding for a fourth CD1 molecule. Proc Natl Acad Sci U S A 86, 252-256.					
	B9	Bendelac, A. (1995). Positive selection of mouse NK1+ T cells by CD1-expressing cortical thymocytes. J Exp Med 182, 2091-2096.					
	B10	Bleicher, P. A., Balk, S. P., Hagen, S. J., Blumberg, R. S., Flotte, T. J., and Terhorst, C. (1990). Expression of murine CD1 on gastrointestinal epithelium. Science 250, 679-682.					
	B11	Blumberg, R. S., Terhorst, C., Bleicher, P., McDermott, F. V., Allan, C. H., Landau, S. B., Trier, J. S., and Balk, S. P. (1991). Expression of a nonpolymorphic MHC class I-like molecule, CD1D, by human intestinal epithelial cells. J Immunol 147, 2518-2524.					
	B12	Borivant, M., Fuss, I. J., Chu, A., and Strober, W. (1998). Oxazolone colitis: A murine model of T helper cell type 2 colitis treatable with antibodies to interleukin 4. J Exp Med 188, 1929-1939.					
	B13	Bonish B, Jullien D, Dutronc Y, Huang BB, Modlin R, Spada FM, Porcelli SA, Nickoloff BJ. Overexpression of CD1d by keratinocytes in psoriasis and CD1d-dependent IFN-gamma production by NK-T cells. J Immunol. 2000 Oct 1;165(7):4076-85.					
	B14	Brown, KD, Zurawski SM, Mosmann TR, Zurawski G. A family of small inducible proteins secreted by leukocytes are members of a new superfamily that includes leukocyte and fibroblast-derived inflammatory agents, growth factors, and indicators of various activation processes J. Immunol. 142 (2), 679-687 (1989).					
	B15	Brown, M. A., and Hural, J. (1997). Functions of IL-4 and control of its expression. Crit Rev Immunol 17, 1-32.					



INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)			Complete if Known	
			Application Number	10/517,898
			Filing Date	14 June 2002
			First Named Inventor	Warren Strober
			Group Art Unit	2123
			Examiner Name	Unassigned
	B16	Brown, TE, Bankhurst AD, Strickland RG. Natural killer cell function and lymphocyte subpopulation profiles in inflammatory bowel disease. J Clin Lab Immunol. 1983 Jul;11(3):113-7.		
	B17	Camoglio L, Te Velde AA, Tigges AJ, Das PK, Van Deventer SJ. Altered expression of interferon-gamma and interleukin-4 in inflammatory bowel disease. Inflamm Bowel Dis. 1998 Nov;4(4):285-90.		
	B18	Ceponis, P. J., Botelho, F., Richards, C. D., and McKay, D. M. (2000). Interleukins 4 and 13 increase intestinal epithelial permeability by a phosphatidylinositol 3-kinase pathway. Lack of evidence for STAT 6 involvement. J Biol Chem 275, 29132-29137.		
	B19	Chen, H., and Paul, W. E. (1997). Cultured NK1.1+ CD4+ T cells produce large amounts of IL-4 and IFN- gamma upon activation by anti-CD3 or CD1. J Immunol 159, 2240-2249.		
	B20	Cui, J., Shin, T., Kawano, T., Sato, H., Kondo, E., Toura, I., Kaneko, Y., Koseki, H., Kanno, M., and Taniguchi, M. (1997). Requirement for Valpha14 NKT cells in IL-12-mediated rejection of tumors. Science 278, 1623-1626.		
	B21	del Mar Cabrera M, Valle J, Pajares JM, Romero I, Zomeno M, Mate J. Expression of the Kp43 (CD 94) receptor by natural killer (NK) cells in ulcerative colitis. Hepatogastroenterology. 2001 Sep-Oct;48(41):1316-20.		
	B22	Desreumaux P, Brandt E, Gambiez L, Emilie D, Geboes K, Klein O, Ectors N, Cortot A, Capron M, Colombel JF. Distinct cytokine patterns in early and chronic ileal lesions of Crohn's disease. Gastroenterology. 1997 Jul;113(1):118-26.		
	B23	Dolganov, et al. "Coexpression of the interleukin-13 and interleukin-4 genes correlates with their physical linkage in the cytokine gene cluster on human chromosome 5q23-31" Blood 87 (8), 3316-3326 (1996).		
	B24	Donaldson, D. D., Whitters, M. J., Fitz, L. J., Neben, T. Y., Finnerty, H., Henderson, S. L., O'Hara, R. M., Jr., Beier, D. R., Turner, K. J., Wood, C. R., and Collins, M. (1998). The murine IL-13 receptor alpha 2: molecular cloning, characterization, and comparison with murine IL-13 receptor alpha 1. J Immunol 161, 2317-2324.		
	B25	Fiocchi C, Tubbs RR, Youngman KR. Human intestinal mucosal mononuclear cells exhibit lymphokine-activated killer cell activity. Gastroenterology. 1985 Mar;88(3):625-37.		
	B26	Fiorentino, D. F., Zlotnik, A., Vieira, P., Mosmann, T. R., Howard, M., Moore, K. W., and O'Garra, A. (1991). IL-10 acts on the antigen-presenting cell to inhibit cytokine production by Th1 cells. J Immunol 146, 3444-3451.		
	B27	Fort, M. M., Cheung, J., Yen, D., Li, J., Zurawski, S. M., Lo, S., Menon, S., Clifford, T., Hunte, B., Lesley, R., et al. (2001). IL-25 induces IL-4, IL-5, and IL-13 and Th2-associated pathologies in vivo. Immunity 15, 985-995.		
	B28	Fuss, I. J., Neurath, M., Boirivant, M., Klein, J. S., de la Motte, C., Strong, S. A., Fiocchi, C., and Strober, W. (1996). Disparate CD4+ lamina propria (LP) lymphokine secretion profiles in inflammatory bowel disease. Crohn's disease LP cells manifest increased secretion of IFN-gamma, whereas ulcerative colitis LP cells manifest increased secretion of IL-5. J Immunol 157, 1261-1270.		



INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)			Complete if Known	
			Application Number	10/517,898
			Filing Date	14 June 2002
			First Named Inventor	Warren Strober
			Group Art Unit	2123
			Examiner Name	Unassigned
	B29	Ginsburg CH, Dambraskas JT, Ault KA, Falchuk ZM. Impaired natural killer cell activity in patients with inflammatory bowel disease: evidence for a qualitative defect. Gastroenterology. 1983 Oct;85(4):846-51.		
	B30	Gumperz, J. E., Roy, C., Makowska, A., Lum, D., Sugita, M., Podrebarac, T., Koezuka, Y., Porcelli, S. A., Cardell, S., Brenner, M. B., and Behar, S. M. (2000). Murine CD1d-restricted T cell recognition of cellular lipids. Immunity 12, 211-221.		
	B31	Hayakawa, K., Lin, B. T., and Hardy, R. R. (1992). Murine thymic CD4+ T cell subsets: a subset (Thy0) that secretes diverse cytokines and overexpresses the V beta 8 T cell receptor gene family. J Exp Med 176, 269-274.		
	B32	Inoue S, Matsumoto T, Iida M, Mizuno M, Kuroki F, Hoshika K, Shimizu M. Characterization of cytokine expression in the rectal mucosa of ulcerative colitis: correlation with disease activity. Am J Gastroenterol. 1999 Sep;94(9):2441-6.		
	B33	Ishikawa, H., Hisaeda, H., Taniguchi, M., Nakayama, T., Sakai, T., Maekawa, Y., Nakano, Y., Zhang, M., Zhang, T., Nishitani, M., et al. (2000). CD4(+) v(alpha)14 NKT cells play a crucial role in an early stage of protective immunity against infection with Leishmania major. Int Immunol 12, 1267-1274.		
	B34	Kadivar K, Defelice ML, Markowitz JE, Baldassano RN, Brown KA. Intestinal interleukin-13 in pediatric inflammatory bowel disease patients. [abstract]. J. Pediatr Gastroenterol Nutr. 2001 33(3):372.		
	B35	Kaneko, Y., Harada, M., Kawano, T., Yamashita, M., Shibata, Y., Gejyo, F., Nakayama, T., and Taniguchi, M. (2000). Augmentation of Valpha14 NKT cell-mediated cytotoxicity by interleukin 4 in an autocrine mechanism resulting in the development of concanavalin A-induced hepatitis. J Exp Med 191, 105-114.		
	B36	Kawano, T., Cui, J., Koezuka, Y., Toura, I., Kaneko, Y., Motoki, K., Ueno, H., Nakagawa, R., Sato, H., Kondo, E., et al. (1997). CD1d-restricted and TCR-mediated activation of valpha14 NKT cells by glycosylceramides. Science 278, 1626-1629.		
	B37	Koyasu, S. (1994). CD3+CD16+NK1.1+B220+ large granular lymphocytes arise from both alpha-beta TCR+CD4-CD8- and gamma-delta TCR+CD4-CD8- cells. J Exp Med 179, 1957-1972.		
	B38	Kucharzik T, Lugering N, Adolf M, Domschke W, Stoll R. Synergistic effect of immunoregulatory cytokines on peripheral blood monocytes from patients with inflammatory bowel disease. Dig Dis Sci. 1997 Apr;42(4):805-12.		
	B39	Kumar, H., Belperron, A., Barthold, S. W., and Bockenstedt, L. K. (2000). Cutting edge: CD1d deficiency impairs murine host defense against the spirochete, Borrelia burgdorferi. J Immunol 165, 4797-4801.		
	B40	Lakatos L. Immunology of inflammatory bowel diseases. Acta Physiol Hung. 2000;87(4):355-72.		
	B41	Lantz, O., and Bendelac, A. (1994). An invariant T cell receptor alpha chain is used by a unique subset of major histocompatibility complex class I-specific CD4+ and CD4-8- T cells in mice and humans. J Exp Med 180, 1097-1106.		
	B42	Lee, P. T., Benlagha, K., Teyton, L., and Bendelac, A. (2002). Distinct functional lineages of human V(alpha)24 natural killer T cells. J Exp Med 195, 637-641.		



INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)			Complete if Known	
			Application Number	10/517,898
			Filing Date	14 June 2002
			First Named Inventor	Warren Strober
			Group Art Unit	2123
			Examiner Name	Unassigned
	B43	Lugering N, Kucharzik T, Stein H, Winde G, Lugering A, Hasilik A, Domschke W, Stoll R. IL-10 synergizes with IL-4 and IL-13 in inhibiting lysosomal enzyme secretion by human monocytes and lamina propria mononuclear cells from patients with inflammatory bowel disease. Dig Dis Sci. 1998 Apr;43(4):706-14.		
	B44	Mack DR, Beedle S, Warren J, Davis J, Gross T. Peripheral blood intracellular cytokine analysis in children newly diagnosed with inflammatory bowel disease. Pediatr Res. 2002 Mar;51(3):328-32.		
	B45	Manzano L, Alvarez-Mon M, Abreu L, Antonio Vargas J, de la Morena E, Corugedo F, Durantez A. Functional impairment of natural killer cells in active ulcerative colitis: reversion of the defective natural killer activity by interleukin 2. Gut. 1992 Feb;33(2):246-51.		
	B46	Minty, A., Asselin, S., Bensussan, A., Shire, D., Vita, N., Vyakarnam, A., Wijdenes, J., Ferrara, P., and Caput, D. (1997). The related cytokines interleukin-13 and interleukin-4 are distinguished by differential production and differential effects on T lymphocytes. Eur Cytokine Netw 8, 203-213.		
	B47	Miyamoto, K., Miyake, S., and Yamamura, T. (2001). A synthetic glycolipid prevents autoimmune encephalomyelitis by inducing TH2 bias of natural killer T cells. Nature 413, 531-534.		
	B48	Mizoguchi, A., Mizoguchi, E., and Bhan, A. K. (1999). The critical role of interleukin 4 but not interferon gamma in the pathogenesis of colitis in T-cell receptor alpha mutant mice. Gastroenterology 116, 320-326.		
	B49	Moore, K. W., O'Garra, A., de Waal Malefyt, R., Vieira, P., and Mosmann, T. R. (1993). Interleukin-10. Annu Rev Immunol 11, 165-190.		
	B50	Neurath, M. F., Fuss, I., Kelsall, B. L., Stuber, E., and Strober, W. (1995). Antibodies to interleukin 12 abrogate established experimental colitis in mice. J Exp Med 182, 1281-1290.		
	B51	Park, S. H., Roark, J. H., and Bendelac, A. (1998). Tissue-specific recognition of mouse CD1 molecules. J Immunol 160, 3128-3134.		
	B52	Parronchi, P., Romagnani, P., Annunziato, F., Sampognaro, S., Beccchio, A., Giannarini, L., Maggi, E., Pupilli, C., Tonelli, F., and Romagnani, S. (1997). Type 1 T-helper cell predominance and interleukin-12 expression in the gut of patients with Crohn's disease. Am J Pathol 150, 823-832.		
	B53	Radford-Smith G, Jewell DP. Cytokines and inflammatory bowel disease. Baillieres Clin Gastroenterol. 1996 Mar;10(1):151-64.		
	B54	Roark, J. H., Park, S. H., Jayawardena, J., Kavita, U., Shannon, M., and Bendelac, A. (1998). CD1.1 expression by mouse antigen-presenting cells and marginal zone B cells. J Immunol 160, 3121-3127.		
	B55	Rogler G, Andus T. Cytokines in inflammatory bowel disease. World J Surg. 1998 Apr;22(4):382-9.		
	B56	Sartor, R. B. (1995). Current concepts of the etiology and pathogenesis of ulcerative colitis and Crohn's disease. Gastroenterol Clin North Am 24, 475-507.		



INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)			Complete if Known	
			Application Number	10/517,898
			Filing Date	14 June 2002
			First Named Inventor	Warren Strober
			Group Art Unit	2123
			Examiner Name	Unassigned
	B57	Saubermann LJ, Beck P, De Jong YP, Pitman RS, Ryan MS, Kim HS, Exley M, Snapper S, Balk SP, Hagen SJ, Kanauchi O, Motoki K, Sakai T, Terhorst C, Koezuka Y, Podolsky DK, Blumberg RS. Activation of natural killer T cells by alpha-galactosylceramide in the presence of CD1d provides protection against colitis in mice. Gastroenterology. 2000 Jul;119(1):119-28.		
	B58	Scheiffele, F., Fuss, I. (2002). Induction of TNBS colitis in mice, Vol 15.19, John Wiley & Sons, Inc.).		
	B59	Shinoda M, Haruta J, Tanimoto M, Ando T, Hosokawa T, Ina K, Kusugami K. Lamina propria mononuclear cells express and respond to interleukin-2 differently in Crohn's disease and ulcerative colitis. Intern Med. 1996 Sep;35(9):679-85.		
	B60	Singh B, Powrie F, Mortensen NJ. Immune therapy in inflammatory bowel disease and models of colitis. Br J Surg. 2001 Dec;88(12):1558-69.		
	B61	Smiley, S. T., Kaplan, M. H., and Grusby, M. J. (1997). Immunoglobulin E production in the absence of interleukin-4-secreting CD1-dependent cells. Science 275, 977-979.		
	B62	Sonoda, K. H., Exley, M., Snapper, S., Balk, S. P., and Stein-Streilein, J. (1999). CD1-reactive natural killer T cells are required for development of systemic tolerance through an immune-privileged site. J Exp Med 190, 1215-1226.		
	B63	Spada, F. M., Koezuka, Y., and Porcelli, S. A. (1998). CD1d-restricted recognition of synthetic glycolipid antigens by human natural killer T cells. J Exp Med 188, 1529-1534.		
	B64	Strober W, Fuss IJ, Blumberg RS. The immunology of mucosal models of inflammation. Annu Rev Immunol. 2002;20:495-549. Epub 2001 Oct 4.		
	B65	Strober, S., Cheng, L., Zeng, D., Palathumpat, R., Dejbakhsh-Jones, S., Huie, P., and Sibley, R. (1996). Double negative (CD4-CD8- alpha beta+) T cells which promote tolerance induction and regulate autoimmunity. Immunol Rev 149, 217--230.		
	B66	Takeda, K., Hayakawa, Y., Van Kaer, L., Matsuda, H., Yagita, H., and Okumura, K. (2000). Critical contribution of liver natural killer T cells to a murine model of hepatitis. Proc Natl Acad Sci U S A 97, 5498-5503.		
	B67	Tamura J, Jinbo T, Itoh K, Take H, Matsushima T, Murakami H, Kubota K, Tsuchiya J, Naruse T. Suppressed natural killer cell activity in ulcerative colitis. J Med. 1994;25(5):337-40.		
	B68	Terabe, M., Matsui, S., Noben-Trauth, N., Chen, H., Watson, C., Donaldson, D. D., Carbone, D. P., Paul, W. E., and Berzofsky, J. A. (2000). NKT cell-mediated repression of tumor immunosurveillance by IL-13 and the IL-4R-STAT6 pathway. Nat Immunol 1, 515-520.		
	B69	Urban, J. F., Jr., Noben-Trauth, N., Donaldson, D. D., Madden, K. B., Morris, S. C., Collins, M., and Finkelman, F. D. (1998). IL-13, IL-4Ralpha, and Stat6 are required for the expulsion of the gastrointestinal nematode parasite Nippostrongylus brasiliensis. Immunity 8, 255-264.		
	B70	Vainer B, Nielsen OH, Hendel J, Horn T, Kirman I. Colonic expression and synthesis of interleukin 13 and interleukin 15 in inflammatory bowel disease. Cytokine. 2000 Oct;12(10):1531-6.		



INFORMATION DISCLOSURE STATEMENT LIST (Use as many sheets as necessary)		Complete if Known	
		Application Number	10/517,898
		Filing Date	14 June 2002
		First Named Inventor	Warren Strober
		Group Art Unit	2123
		Examiner Name	Unassigned
	B71	van Tol EA, Verspaget HW, Pena AS, Lamers CB. Normal inflammatory bowel disease mucosa conceals alterations in natural killer cell activity. Scand J Gastroenterol. 1992 Dec;27(12):999-1005.	
	B72	Vezys, V., Olson, S., and Lefrancois, L. (2000). Expression of intestine-specific antigen reveals novel pathways of CD8 T cell tolerance induction. Immunity 12, 505-514.	
	B73	Wills-Karp, M., Luyimbazi, J., Xu, X., Schofield, B., Neben, T. Y., Karp, C. L., and Donaldson, D. D. (1998). Interleukin-13: central mediator of allergic asthma. Science 282, 2258-2261.	
	B74	Yoshimoto, T., and Paul, W. E. (1994). CD4pos, NK1.1pos T cells promptly produce interleukin 4 in response to in vivo challenge with anti-CD3. J Exp Med 179, 1285-1295.	
	B75	Zurawski, G., and de Vries, J. E. (1994). Interleukin 13, an interleukin 4-like cytokine that acts on monocytes and B cells, but not on T cells. Immunol Today 15, 19-26.	
Examiner Signature:		Date Considered:	
EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.			